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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,389	07/22/2003	Mark C. Estes	PF01022 US	6826

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EXAMINER	
DESANTO, MATTHEW F	
ART UNIT	PAPER NUMBER
3763	
MAIL DATE	DELIVERY MODE
01/08/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/624,389	ESTES ET AL.	
	Examiner	Art Unit	
	MATTHEW F. DESANTO	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,10-74 and 95* is/are pending in the application.

4a) Of the above claim(s) *35-74* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,10-34 and 95* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 1 is ambiguous and unclear because of the newly amended limitations because of the language "is recent enough." The examiner is unsure how to interpret "recent enough" since this can be anything from a minute to several hours, and thus makes the claim indefinite since upper and low limits haven't been claim on this range.

Terminal Disclaimer

4. The terminal disclaimer filed on 10/12/09 disclaiming the terminal portion of any patent granted on this application has been reviewed and is NOT accepted.

> a. The person who signed the terminal disclaimer is not recognized as an officer of the assignee, and he/she has not been established as being authorized to act on behalf of the assignee. See MPEP § 324.

5. An attorney or agent, not of record, is not authorized to sign a terminal disclaimer in the capacity as an attorney or agent acting in a representative capacity as provided by 37 CFR 1.34 (a). See 37 CFR 1.321(b) and/or (c).

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-6, 10-34 and 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell et al. (US 20030060765) as applied to claims cited in the office action dated 3/7/07, in view of Galley et al. (USPN 6,544,212) and further in view of Jones (US 20030211617) .

3. Campbell et al. discloses an infusion device with a characteristic determining device and an infusing device as well as all the particulars of the claims except for a program that determines the analyte levels over time and recalculates the delivery profile in accordance with the levels of analyte and associates a “timestamp" or time with the concentration.

4. Gallery et al. discloses a system for providing glycemic control that has a processor that deals with conducting glucose measurements and the using the processor to what the future glucose levels will be as well as measuring the glucose levels over time and then determining the delivery profile based on the readings and algorithm (entire reference). Gallery et al. discloses two algorithms that include a feedback algorithm and a feedforward algorithm, which determined the infusion rate. The infusion rate is only determined after results of the algorithm and thus wouldn't be calculated if the glucose levels were within there proper range.

5. Jones discloses a metering device with a program that couples a time interval with a glucose reading. The software program allows a predetermined time interval to be set which will alert the user when the set time interval has elapsed and the data

(blood glucose) that was sensed or entered is no longer reliable and a new reading must be taken [0011][0014][0015][0018][0037][0038][0044][0045].

6. At the time of the invention it would have been obvious for one of ordinary skill in the art to combine the device of Campbell et al. with the teachings of Gallery et al. because Gallery et al. discloses a more effective treatment method for diabetes because of the constant feedback provided by the algorithms and it would further have been obvious to add the software program of Jones to ensure that a proper glucose concentration is being used to determine if the user needs insulin or another type of treatment (Jones – par [0011]-[0016]) as well as using the timestamp to control the infusion patterns, rates and calculations, since the user would want the most accurate and precise glucose concentration. The teachings of Jones also provides another benefit which is that the user gets reminded when another test must be taken, which provides for a more user friendly device.

7. Claims 1-6, 10-34 and 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Estes et al. (US 20030114836) as applied to claims cited in the office action dated 3/7/07, in view of Galley et al. (USPN 6,544,212) and further in view of Jones (US 20030211617).

8. Estes et al. discloses an infusion device with a characteristic determining device and an infusing device as well as all the particulars of the claims except for a program that determines the analyte levels over time and recalculates the delivery profile in accordance with the levels of analyte and associates a “timestamp" or time with the concentration.

9. Gallery et al. discloses a system for providing glycemic control that has a processor that deals with conducting glucose measurements and the using the processor to what the future glucose levels will be as well as measuring the glucose levels over time and then determining the delivery profile based on the readings and algorithm (entire reference). Gallery et al. discloses two algorithms that include a feedback algorithm and a feedforward algorithm, which determined the infusion rate. The infusion rate is only determined after results of the algorithm and thus wouldn't be calculated if the glucose levels were within there proper range.

10. Jones discloses a metering device with a program that couples a time interval with a glucose reading. The software program allows a predetermined time interval to be set which will alert the user when the set time interval has elapsed and the data (blood glucose) that was sensed or entered is no longer reliable and a new reading must be taken [0011][0014][0015][0018][0037][0038][0044][0045].

11. At the time of the invention it would have been obvious for one of ordinary skill in the art to combine the device of Estes et al. with the teachings of Gallery et al. because Gallery et al. discloses a more effective treatment method for diabetes because of the constant feedback provided by the algorithms and it would further have been obvious to add the software program of Jones to ensure that a proper glucose concentration is being used to determine if the user needs insulin or another type of treatment (Jones – par [0011]-[0016]) as well as using the timestamp to control the infusion patterns, rates and calculations, since the user would want the most accurate and precise glucose concentration. The teachings of Jones also provides another benefit which is that the

user gets reminded when another test must be taken, which provides for a more user friendly device.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 1-6, 10-34, 95 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 7,278,983. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim a infusion device and an characteristic determining device that associates time with the data that is sensed by the determined device.

Response to Arguments

14. Applicant's arguments with respect to claims have been considered but are not persuasive with regards to the previous rejections.

15. The applicant arguments drawn to the newly added limitations are considered but unpersuasive because of the indefinite of the language. The examiner is unsure how recent the data needs to be in order to calculate the concentration of analyte since information provides the critical step in the claimed invention. The examiner cites Campbell as the primary reference that teaches a bolus estimator that estimates the bolus needed based on the blood glucose measurement (para 0090) as well as associating the levels of analyte with a time stamp. The examiner then cites Gallery et al. and Jones as secondary references since Gallery et al. discloses ways to control the bolus injection based on ranges and if the data fails within that range then no action is needed and if the data fails out the range then action is needed. Gallery et al. also discloses estimating the amount insulin needed depending on the "sensitivity" which is the change in glucose level at a time and then taking action depending on the outcome. Jones discloses a time related glucose monitoring device that reminds user to retest depending on events and time that has elapsed since the last test. Therefore when these references are combined one of ordinary skill in the art would have a better understand of how to control and monitor a patient under time and relate that with a bolus estimator, since Jones discloses the benefit of monitoring after an event or when a certain amount of time has elapsed since this will give a more accurate measurement, and Gallery et al. discloses the benefit of using a bolus injection only when needed and when the estimator has determined that it would be beneficial, thus when combining Campbell that teaches a bolus estimator with the software from Gallery et al. and Jones, it would have been obvious to determine if the data measure was accurate because of

the teachings from Jones and thus control the delivery device based on the teachings from Campbell et al. and Gallery et al.

16. Estes teaches a similar delivery device as Campbell et al. and thus would be modified with Gallery et al. and Jones as described above.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW F. DESANTO whose telephone number is (571)272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Matthew DeSanto
/Matthew F DeSanto/
Primary Examiner, Art Unit 3763